US-English speaking and 16 US-Spanish speaking participants with primary or secondary insomnia. Data for the validation of the SIS were collected alongside a North American 4-week multicenter, double-blind, placebo-controlled, randomized, parallel-group study in primary and secondary insomnia patients. Item level analyses including assessment of missing data, item-item correlations, Principal Components Analysis, and clinical validity were conducted. Items with floor or ceiling effects were candidates for deletion, as were items which did not load with any particular domain. Once domains were determined, validity of the domains was assessed through internal consistency reliability, item-domain concurrent and divergent validity, clinical validity, concurrent validity and confirmatory factor analysis. Additionally, responsiveness and minimal important difference estimates were determined. **RESULTS:** Patient interviews resulted in 55 items in 8 domains. During item reduction and validation, 18 items were deleted based on their content validity, high ceiling effect (>40%), redundancy (Inter-item Pearson correlation > 00.80) no or multifactor loading and/or failure to meet the Item-level discriminant validity criterion. After reduction, the final SIS consists of 35 items in 7 domains. **CONCLUSION:** The SIS was developed to account for US-English and US-Spanish cultural differences. The validation study provides evidence on the psychometric properties of the SIS. The SIS has been shown to adequately meet the criteria for a validated measure to be used in clinical trials.

PMH56

A REVIEW OF INSTRUMENTS USED TO ASSESS THE IMPACT OF ALCOHOLISM ON QUALITY OF LIFE

Reaney M[1], Martin C[2], Speight J[1]
[1]AHP Research Ltd, Uxbridge, Middlesex, UK, [2]Leeds Metropolitan University, Leeds, Leeds, UK

OBJECTIVES: To comprehensively explore existing quality of life (QoL) measures in alcoholism (alcohol abuse and alcohol dependence). **METHODS:** Systematic searches of Scopus (1990–2007) were conducted using terms synonymous with alcoholism combined with terms associated with measuring QoL. **RESULTS:** In total, 618 abstracts were identified detailing the use of 16 generic patient-reported measures to assess QoL in alcoholism. Upon further examination (ie searching Scopus using the QoL measure as a search term from date of development) nine measured health status and seven assessed generic QoL, with varying definitional criteria and domain focus. The SF-36 and EQ-5D, in particular, have been used widely but frequently misinterpreted as measures of QoL rather than health status. One alcohol-specific QoL measure was identified; the AlQoL 9, a scale that the authors have claimed to epitomise alcohol-related QoL. However, the AlQoL 9 was developed by reducing the SF-36 (French version) to the nine items most relevant to alcoholism. The methodology for determining the relevance of the existing items of the SF-36 was comprehensive but the adapted measure does not include assessment of additional concepts (such as sleep and social isolation) of particular importance for alcohol-related QoL. **CONCLUSION:** There is a lack of research and assessment of QoL in alcoholism. Individuals need to be given the opportunity to determine the extent to which their QoL is impaired by alcoholism based upon their own criteria for what constitutes good QoL. There is a need for an alcoholism-specific QoL measure, which focuses on the domains that are most salient to people with such problems. Furthermore, research that includes an assessment of the impact of alcoholism on the QoL of friends, family and colleagues of the person abusing alcohol would also be valuable. Only then will we be able to assess the full impact of alcoholism (and its treatment) on QoL.

PMH57

EFFECTIVENESS OF A PSYCHOSOCIAL INTERVENTION PROGRAM FOR CAREGIVERS OF PATIENTS WITH ALZHEIMER'S DISEASE IN THE PREVENTION OR REDUCTION CAREGIVER BURDEN EDUCA STUDY

Balañá M[1], Martín M[2], Pons S[3], Gobartt AL[1]
[1]Novartis Pharmaceuticals, Barcelona, Spain, [2]Clinica Padre Menni, Pamplona, Spain, [3]Laboratorios Esteve, Barcelona, Spain

OBJECTIVES: Caregivers's patients with Alzheimer's disease (AD) experience physical and psychical stress due to the caring. This study evaluated the benefits of a Psychosocial Intervention Program (PIP) on caregivers' burden **METHODS:** A epidemiological, prospective, randomized, multicenter study was conducted by psychiatrists who recruited 115 primary caregivers's of patients with AD (DMS-IV criteria and MMSE score = 10–26) and at least 2 impaired instrumental activities of daily living (IADL score) by Lawton & Brody Test. Caregivers were randomized to receive either PIP (intervention group (IG), n = 60) or standard care (control group (CG), n = 55). PIP consisted on individual sessions (scheduled every 1–2 weeks during 4 months) of teaching strategies to reduce caregiver burnout. Caregivers stress, quality of life (QoL) and perceived health were measured using validated scales (Zarit, SF-36, GHQ-28) at baseline, after a 4-month and a 10-month follow-up period **RESULTS:** The profile of patient with AD was a 77-years-old woman, with moderate dementia (MMSEscore = 18.74) and high impairment of daily living activities (mean IADLscore = 2.17). The caregiver profile was a 60-years-old woman, wife or adult daughter, who is being careing for 3 years and care daily time was >12 hours, without refund. Changes in caregiver burden (baseline Zaritscore–final Zaritscore) showed an improvement in the IG (−8.09 points) and a worsening grouping the CG (+2.08 points), with statistically significance (p = 0.0083). The IG showed significant improvements in all the well-being perception areas measured by the SF-36scores and significantly lower score in the GHQ-28score (p = 0.0004). Caregivers and therapists considered PIP "useful/very useful" in a 97.7% and 88.6% respectively at the end of PIP, and in a 93.2% and 86.3% at 6 moths after PIP ending. **CONCLUSION:** Caregivers' psychosocial training can minimize caregiver distress and may help to develop strategies for coping problems. PIP improves QoL and the perceived health of caregivers of patients with AD.

PMH58

IMPROVED SLEEP IMPACT IN GENERALIZED ANXIETY DISORDER WITH ZOLPIDEM TARTRATE EXTENDED-RELEASE

Crawford B[1], Zhu Y[1], Seal B[2], Rosa K[1]
[1]Mapi Values, Boston, MA, USA, [2]Sanofi-Aventis, Bridgewater, NJ, USA

OBJECTIVES: Insomnia is frequently associated with generalized anxiety disorder (GAD) and affects the patient's day to day life. The Sleep Impact Scale (SIS) was developed to assess the impact of insomnia; however it has not been used in GAD. Therefore, a study was conducted to validate the SIS and evaluate the impact of zolpidem tartrate extended-release on insomnia in GAD. **METHODS:** Validation and efficacy data of the SIS were collected alongside a randomized, placebo-controlled trial of escitalopram + placebo or zolpidem tartrate extended-release in adults with insomnia associated with GAD. The validation consisted of evaluation of the validity and reliability, the responsiveness and the MID of the SIS domains to ensure the questionnaire was acceptable in a GAD population. The efficacy analysis was performed on the ITT population, consisting of general linear models to evaluate changes from baseline at each timepoint, with study endpoint as the primary change score analysis. Longitudinal analyses were also performed to evaluate the effects of